IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

MARIA LUISA GARZA and **OSCAR GARZA, SR.,**	§	
Plaintiffs,	§	
v.	§	**CIVIL ACTION NO. 2:12-CV-00198**
WYETH LLC, et al.,	§	
Defendants.	§	

ORDER GRANTING DEFENDANT TEVA'S MOTION FOR SUMMARY JUDGMENT

Before the Court is Defendant Teva Pharmaceuticals USA, Inc.'s Motion for Summary Judgment. (D.E. 90.) For the reasons set forth below, Defendant's motion is GRANTED.

SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). The Court must consider the affidavits, depositions, declarations, stipulations, and other documents presented to the Court in the light most favorable to the non-movant. *Caboni v. General Motors Corp.*, 278 F.3d 448, 451 (5th Cir. 2002). The substantive law identifies which facts are material. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *Ellison v. Software Spectrum, Inc.*, 85 F.3d 187, 189 (5th Cir. 1996). A dispute about a material fact is genuine only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson*, 477 U.S. at 248; *Judwin Props., Inc., v. U.S. Fire Ins. Co.*, 973 F.2d 432, 435 (5th Cir. 1992).

SUMMARY JUDGMENT EVIDENCE

With its motion for summary judgment, Defendant Teva provided the Court a statement of undisputed material facts. (D.E. 91 at 5–7.) Additionally, Teva submitted numerous exhibits, including pharmaceutical records, affidavits, and other admissible evidence in support of these facts. (D.E. 92.) Plaintiff does not contest the admissibility of Defendant's summary judgment evidence, dispute the accuracy of Defendant's statement of undisputed material facts, or present any adverse evidence demonstrating the existence of a genuine dispute as to the material facts of this case. Accordingly, the Court considers the facts of this case to be undisputed for purposes of this motion. *See* FED. R. CIV. P. 56(e) ("If a party . . . fails to properly address another party's assertion of fact as required by Rule 56(c), the court may . . . consider the fact undisputed for purposes of the motion . . . .").

STATEMENT OF FACTS

The pharmacy records demonstrate that Ms. Garza was dispensed metoclopramide manufactured by Defendant Teva from July 24, 2006 through April 2, 2009. There is no evidence in the record that Ms. Garza was dispensed generic metoclopramide manufactured by Defendant Teva outside of these dates. As of June 24, 2005, Defendant Teva's metoclopramide label matched the FDA-approved label for the brand-name version of the drug, Reglan metoclopramide, including the 2004 updates to the precautions, indications, and usage section of the labeling, as well as the updates to the dosage and administration section. The FDA did not approve any additional label changes until June 30, 2009. Accordingly, during the period in which Ms. Garza was dispensed generic metoclopramide manufactured by Teva, the drug labels attached to Defendant's product included the most up-to-date safety information and warnings

approved by the FDA regarding the risks of developing tardive dyskinesia due to exposure to metoclopramide.

ANALYSIS

In its motion for summary judgment, Defendant argues that Plaintiffs' failure-to-update and failure-to-communicate claims are preempted by federal law with regard to Teva, and furthermore, that Plaintiffs' claims against Teva are precluded by the presumption of no liability for drug manufacturers in Texas Civil Practice and Remedies Code Section 82.007. (D.E. 91.) The Court agrees and grants summary judgment in favor of Defendant Teva.

In its March 7, 2013 Order Granting in Part and Denying in Part Generic Defendants' Motion to Dismiss, this Court distinguished the facts and theories of liability alleged in the case at hand from those described in *Pliva, Inc. v. Mensing*, 131 S.Ct. 2567 (2011). (D.E. 84 at 6–7.) In *Mensing*, the generic drug manufacturers' labels matched the brand-name manufacturers' FDA-approved labels; whereas, in the case at hand, the generic drug manufacturers labels did not match the labels approved for use on the brand-name form of the drug. The *Mensing* plaintiffs complained that the defendant drug manufacturers should have unilaterally updated their labels to comply with state law and provide a stronger safety warning for consumers. In the case at hand, the Plaintiffs claim that the generic drug manufactures have a duty to update their labels to match the latest changes to the brand-name labels.

In *Mensing*, 131 S.Ct. at 2578, the Supreme Court concluded that a state law requiring generic manufacturers to unilaterally update their labels was preempted by a federal law requiring generic labels to be the same as their corresponding brand-name labels. This "duty of sameness" under federal law prohibits generic drug manufacturers from taking unilateral action

to change their warning labels; generic manufacturers must wait for the FDA and the brand-name manufacturers to take the lead. *Morris v. Pliva, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013).

In the case at hand, Plaintiffs' Fourth Amended Complaint alleged that Generic Defendants failed to update their labels to match FDA-approved changes made to the Reglan metoclopramide label in 2003, 2004, and 2009. (See allegations of Fourth Amended Complaint, D.E. 72 at 9, 18, 23–25.) As it was possible for the Generic Defendants in the case at hand to comply with both state and federal law, Plaintiffs' failure-to-update claims were not preempted under *Mensing*. Moreover, the Court concluded that Plaintiffs' claims were not barred by Section 82.007 of the Texas Civil Practice and Remedies Code because the presumption of no liability only applies where the manufacturer's warnings or information accompanying the product in its distribution were those approved by the FDA. (D.E. 84 at 8.) If Generic Defendants failed to update their labels, then the warnings accompanying the product were not those approved by the FDA.

The undisputed facts of this case now show, however, that Defendant Teva's metoclopramide labels matched the brand-name Reglan manufacturers' FDA-approved labels at all times during the period in which Ms. Garza was dispensed generic metoclopramide manufactured by Defendant Teva. Plaintiffs do not contest this material fact. Consequently, Plaintiffs' failure-to-update claims against generic drug manufacturer Teva are preempted under *Mensing* and/or subject to the rebuttable presumption set forth in Section 82.007.

Plaintiffs argue, however, that Defendant Teva can still be held liable for failing to communicate to Ms. Garza's physician through a "Dear Doctor" letter the strengthened warnings contained in the 2003 and 2004 FDA-approved label updates. (D.E. 94 at 2–7.) This avenue is foreclosed by the Fifth Circuit's recent decision in *Morris*, 713 F.3d at 777. Under *Morris*,

generic manufacturers are required to follow the lead of the brand-name manufacturers with regard to "Dear Doctor" letters as well as label updates.

> *Mensing* forecloses such claims because failure to "communicate" extends beyond just a label change. To avoid liability, the manufacturer must take affirmative steps to alert consumers, doctors, or pharmacists of changes in the drug label. Because the duty of sameness prohibits the generic manufacturers from taking such action unilaterally, they are dependent on brand-names taking the lead. *Id*. at 2576 ("[I]f generic drug manufacturers, but not the brand-name manufacturer, sent [additional warnings such as a 'Dear Doctor' letters], that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.' "). Under federal law, the inquiry is whether the brand-name manufacturers sent out a warning, not whether the proposed warning to be disseminated contains substantially similar information as the label. Because no brand-name manufacturer sent a warning based on the 2004 label change, the generic manufacturers were not at liberty to do so. As *Mensing* concluded, preemption is thus triggered since it would be impossible for PLIVA to comply with both the state law duty to warn and the federal law duty of sameness.

Id. Plaintiffs failed to provide any evidence that the brand-name manufacturers disseminated "Dear Doctor" letters. Accordingly, Plaintiffs' claim that Teva failed to communicate the strengthened warnings is preempted by federal law.

CONCLUSION

For the reasons set forth above, Defendant Teva's Motion for Summary Judgment (D.E. 90) is GRANTED and all remaining claims against Teva are DISMISSED WITH PREJUDICE.

ORDERED this 28th day of June 2013.

NELVA GONZALES RAMOS
UNITED STATES DISTRICT JUDGE